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| 51832 | 7590 | 06/03/2005 | EXAMINER | |
| JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017-6702 | | | RAGONESE, ANDREA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,562

Applicant(s)

WILFORD, TROY

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,25-27 and 33 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,6 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,7-15,17-20,25-27 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on March 11, 2005 has been entered. Examiner acknowledges that **claim 1** has been amended, **claims 21-24 28-32** have been canceled, and **claim 33** has been added. Subsequently, **claims 1, 3, 5, 7-15, 17-20, 25-27** and **33** are under consideration, while **claims 2, 4, 6** and **16** have been withdrawn from further consideration.

Response to Arguments

2. Applicant's arguments filed March 11, 2005 have been fully considered but they are not persuasive. In response to the argument that "the Goble '840 patent does not teach or suggest all of the limitations of claim 1," the Examiner respectfully disagrees. As stated hereinafter, the prior art of record does disclose each and every claim limitation.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claim 33** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No new matter may be entered in an amendment.

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Specifically, the claim limitation, found in **claim 33**, "wherein the opening and the recess are not in communication with one another" cannot be found in the original disclosure of the instant application. Therefore, it is considered new matter and must be canceled from the claim since there is no evidence that this newly claimed invention was possessed by the Applicant at the time the application was filed.

5. **Claim 33** is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This newly filed claim does not have proper support in the originally filed specification of the instant invention to allow one of ordinary skill in the art to make or use the invention as claimed. It is not apparent how the implant body would function if the "opening and the recess" were "not in communication" with one another. As currently depicted in the drawings and described the specification, each and every structural element of the implant body is "in communication" with one another, otherwise, the implant itself would not work.

6. Examiner would like to point out that in the instance that the Applicant were to amend the claim to overcome these rejections under 35 U.S.C. 112, first paragraph, a species restriction, based on election by original presentation, may be required if Applicant were to claim an additional species of the instant invention, other than the one that is currently being examined the merits.

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7. Accordingly, **claim 33** cannot be, and has not been, further treated on the merits since Examiner cannot ascertain the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1, 7-11, 17-20 and 25** are rejected under 35 U.S.C. 102(b) as being anticipated by Goble et al. (US 5,931,840).

Regarding **claim 1**, Goble et al. discloses a fixation device (generally @ 10), as seen in figures 1-5, for securing one end of a graft to bone. The device has an implant body (generally @13) with first and second ends. The first end has an opening (such as 17) configured and adapted for receiving an insertion tool, as recited in columns 7-8, with emphasis on column 7, lines 30-35 and 60-65 as well as column 8, lines 60-68. Column 7, lines 66-67 recite, "Preferably, the proximal cavity 17, as set out above, is sided at 25, to receive the turning tool fitted therein, and to later receive the turning tool for adjusting ligament tensioning..." Applicant is also directed to column 8, lines 60-68, which states the installation via the cavity 17. Further, the implant body (generally @ 13) has a second end that has a recess (such as 15) and a graft interface member (11) having a graft holding portion (generally @ 27) and an implant coupling portion (generally @ 18) having a distal end (generally @ 12) and a proximal end (generally @ 26), the distal end of the coupling portion is configured and fully capable of being

adapted to be received in the recess to permit the implant body to rotate independent of the graft interface member. The proximal end of the coupling portion is configured and fully capable of being adapted to be operably associated with the graft holding portion. Further, the implant-coupling portion has a snap-fit type connection and the graft holding portion has a central longitudinal axis and is configured and adapted to hold a graft aligned with the central longitudinal axis, as recited in columns 6-8 and seen in the figures.

Regarding **claim 7**, Goble et al. discloses that as applied to **claim 1**, as well as, a coupling portion with a flexible post (defined by slots 21), as recited in column 7.

Regarding **claim 8**, Goble et al. discloses that as applied to **claim 7**, as well as, a flexible post that has a flared tip portion (@ 18a and 19), as seen in figure 1.

Regarding **claim 9**, Goble et al. discloses that as applied to **claim 8**, as well as, a flared tip portion that is slotted (@ 21), as seen in figure 1.

Regarding **claim 10**, Goble et al. discloses that as applied to **claim 1**, as well as, a recess in the second opposed end that has an undercut section, as seen in figures 1 and 3A-3C.

Regarding **claim 11**, Goble et al. discloses that as applied to **claim 1**, as well as, an implant body and a graft interface that are integrally connected to each other, as seen in figures 1-3C.

Regarding **claim 17**, Goble et al. discloses that as applied to **claim 1**, as well as, a first opening that is hexagonal, as recited in columns 7-8, with emphasis on column 7, lines 30-33.

Regarding **claims 18 and 19**, Goble et al. discloses that as applied to **claim 1**, as well as an internally threaded implant, as recited in columns 7-8.

Regarding **claim 20**, Goble et al. discloses that as applied to **claim 1**, as well as, an implant body (13) that has an outer surface that at least a portion of which has threads (16) for implantation into bone, as seen in figure 1.

Regarding **claim 25**, Goble et al. discloses that as applied to **claim 1**, as well as, an implant coupling portion (generally @ 18) that is received in the recess from the second end of the implant, as seen in figure 1-3C.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. **Claims 3, 5, 12-15 and 26-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Goble et al. (US 5,931,840) in view of Papay et al. (US 6,517,542).

Regarding **claim 3**, Goble et al. discloses that as applied to **claim 1**. However, Goble et al. do not explicitly recite a graft holding portion that is a cage. On the other hand, Papay et al. teaches a cage structure as seen in figures 15-16, for example. Thus, it would be obvious to one with ordinary skill in the art to modify the structure of Goble et al. to include a cage as taught by Papay et al. for the purpose of enhanced graft placement and securing ability.

Regarding **claim 5**, Goble et al. as modified discloses that as applied to **claim 3**, as well as, Papay et al. further teaches a cage that has a cage bottom portion and a cage top portion attachable to the cage bottom portion, as seen in figures 15-19. Thus, in the modification, it would further be obvious to have the bottom and top portion be attachable.

Regarding **claim 12**, Goble et al. as modified discloses that as applied to **claim 5**, as well as, it is within the scope of the modification and would further be obvious to have a cage top that has at least one detent configured and adapted to attached the cage top portion to the cage bottom portion.

Regarding **claim 13**, Goble et al. as modified discloses that as applied to **claim 12**, as well as, it is within the scope of the modification and would further be obvious to have a cage bottom portion that has at least one fitting configured and adapted to receive the detent.

Regarding **claim 14**, Goble et al. as modified discloses that as applied to **claim 5**, as well as, it is within the scope of the modification and would further be obvious to have a bone cage that has at least one wall portion and the at least one opening through the at least one wall portion.

Regarding **claim 15**, Goble et al. as modified discloses that as applied to **claim 14**, as well as, as well as it is within the scope of the modification and would further be obvious to have a wall portion that has an interior surface having serrations, via the snap fit components.

Regarding **claim 26**, Goble et al. discloses that as applied to **claim 1**. However, Goble et al. does not explicitly recite a graft holding portion that is a cage having at least two separate members, wherein the snap-fit connection defines at least two members and the inside bore is considered part of the cage when in engagement. On the other hand, Papay et al. teaches a cage structure as seen in figures 15-16, for example. Thus, it would be obvious to one with ordinary skill in the art to modify the structure of Goble et al. to include a cage as taught by Papay et al. for the purpose of enhanced graft placement and securing ability. In this modification, it would be further obvious and within the scope to have a snap-fit connection defines at least two members and the inside bore is considered part of the cage when in engagement.

Regarding **claim 27**, Goble et al. as modified discloses that as applied to **claim 26**, as well as, a cage having first and second members that mate is within the scope of the modification.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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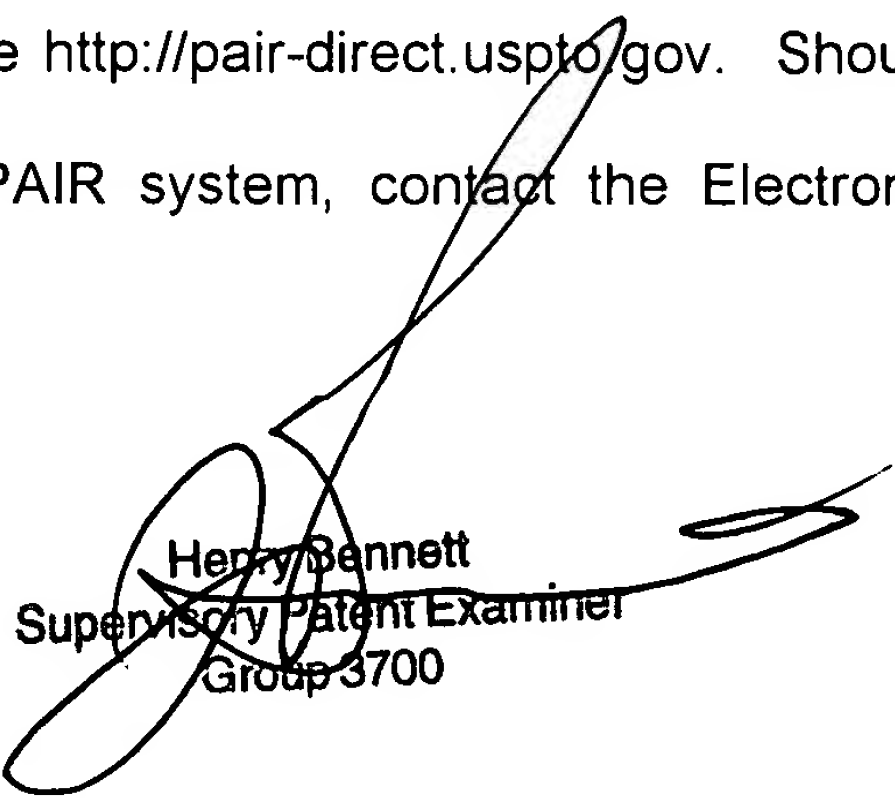
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR
May 31, 2005



Henry A. Bennett
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